# Emerging Trends That Herald the Future of Surgical Simulation

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1. REPORT DATE JUN 2010		2. REPORT TYPE		3. DATES COVERED <b>00-00-2010 to 00-00-2010</b>		
4. TITLE AND SUBTITLE				5a. CONTRACT NUMBER		
Emerging Trends That Herald the Future of Surgical Simulation				5b. GRANT NUMBER		
				5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S)				5d. PROJECT NUMBER		
				5e. TASK NUMBER		
				5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)  University of Washington Medical Center, Department of Surgery, 1959  Pacific Street NE, Seattle, WA, 98195  8. PERFORMING ORGANIZATION REPORT NUMBER						
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)		
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION/AVAILABILITY STATEMENT  Approved for public release; distribution unlimited						
13. SUPPLEMENTARY NOTES  Volume 90, Issue 3, June 2010, Pages 623-633, Simulation and Surgical Competency						
14. ABSTRACT						
15. SUBJECT TERMS						
16. SECURITY CLASSIFIC	17. LIMITATION OF	18. NUMBER	19a. NAME OF			
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified	Same as Report (SAR)	OF PAGES 22	RESPONSIBLE PERSON	

**Report Documentation Page** 

Form Approved OMB No. 0704-0188

## **SYNOPSIS**

For the first time in over 100 years, there is a revolution in surgical education. One of the most important core technologies that are generating this revolution is simulation science, which includes not only the technology of simulators, but new curricula, objective assessment methods and criterion-based requirements. By reviewing the current status of simulation, and comparing to the emerging technologies, an analysis of the gaps can demonstrate the necessary direction for the future.

## INTRODUCTION

There is now an acceptance, based upon validated curricula and simulators (1), that patient safety is improved through simulation-based training. This acceptance is based upon the recent adoption of a myriad of simulation technologies and a revolution in surgical education. The last such revolution was 100 years ago with the Flexner report (2) in 1910 which was driven by a need to change the apprenticeship model toward a more consistent and comprehensive training model through the establishment of more formal residency training programs. Although significant, this change continued the emphasis on training the surgeon rather than on patient safety.

This has evolved into the current process of training and evaluation of surgeons, based upon subjective judgment (and a few objective measures such question and answer, case based discourse, tests, etc.) which focused upon knowledge. Skills based training and assessment has previously been accomplished exclusively by subjective appraisal in the hospital or operating room or based upon the number of surgical procedures (without any measures of performance).

We are in the midst of a new revolution in surgical education which is being "opportunity driven" by external forces – principally by the introduction of new technologies and the political desire to ensure patient safety. The political forces have been caused by both a more informed public (patients) as well as healthcare activism. These issues are critical in the acceptance of changes, but will not be addressed herein. The technologies, principally in simulation (broadly defined) include not only 'simulators', but also the curricula with assessment tools. It is the convergence of these two aspects, the introduction of simulation for skills training and the structured objective assessment of skills performance (including cognitive skills such as communication, etc) with benchmark metrics that has enabled simulation to transform surgical education from subjective judgment to objective measurement of performance.

The traditional psychomotor skills simulation technology has been based upon physical models, animal parts (pig trotters, rendered intestines, etc), while the emerging simulation employs manikins, recent computer-based interactive programs, and a variety of virtual reality (VR) simulations, with variations such as full head-mounted displays, augmented reality, and hybrid VR with physical models. The new curricula have been focused upon basic skills, a few advanced skills and team training. Within the past decade, patient actors have begun to be used to teach elements of history and physical examination, as well as assessment of communication skills and professionalism in what is termed Objective Structured Clinical Exam (OSCE). In 1997, Resnick et al. (3) developed a formalize curriculum methodology to quantitatively assess performance of psychomotor skills, entitled the Objective Structured Assessment of Technical Skills (OSATS). The following year, Fried et al adapted the

methodology to a specific curriculum for laparoscopic surgery, called the Fundamentals of Laparoscopic Surgery (FLS) (4). Together, the OSCE and OSATS have turned the subjective training and evaluation of psychomotor, cognitive and communication skills into a method of quantifying performance with measurable results. But even more important is the fact that, by measuring the performance of experienced and expert surgeons with these methods, benchmarks of competent performance could be established. This has led to the profound revolution of "training to proficiency" (or competency), meaning that residents are no longer trained for a specified time (i.e. a few days) before performing a procedure on patients. Instead the residents are trained for whatever length of time is required to reach the benchmark measures, with some residents finishing faster and others taking longer; however no resident is permitted to perform a procedure upon a patient until the criterion benchmark is reached. While this change in education does not guarantee patient safety, it clearly improves patient safety, as has been demonstrated in numerous studies on the reduction of errors and improvement in the efficiency after training on a simulator. This should come as no surprise, since most other professions (such as aviation, military, etc) have been using these methods for decades.

## MANDATES

As indicated above, it has taken over 15 years since the beginning of the first surgical simulators (5) to acquire enough evidence to prove the effectiveness of training using simulators with objective assessment to proficiency (1). The result has been that the surgical education and certifying community has issued mandates which require the implementation of surgical simulation into residency training. The first such mandate

came in 2003 from the Accreditation Council on Graduate Medical Education (ACGME), in conjunction with the American Board of Medical Specialties (ABMS) by redefining in precise terms the six competencies that must be taught, measured and certified. They are: Knowledge, patient care, communication and interpersonal skills, professionalism, systems-based practice, and lifelong learning. It is noted that only the first two competencies had traditionally been formally taught. The remainder had either been informally taught during rounds or in the OR, or had not even been acknowledged as important aspects of surgical education.

In 2008, the second mandate was issued by the surgical Residency Review Committee (RRC) of the ACGME (6). This requires that all surgical residency programs must have access to "... simulation and skills laboratories". The implications of this mandate are profound, once again emphasizing the importance of quantifiable skills training in the safe environment of a laboratory setting – it is no longer acceptable to "practice on" a patient, rather skills competency must first be learned through simulation.

In 2009, the third mandate was issued by the American Board of Surgery (ABS) (7). Convinced of the significant improvement in training and in safety as demonstrated by analogy to other industries which use simulation, and by the unequivocal validation of FLS, the ABS now requires that applicants for "... the General Surgery Qualifying Examination must ... provide documentation of successful completion [of FLS] with their application". Otherwise the application will be considered incomplete, and returned to the candidate who will not be permitted to sit for the examination to receive ABS Certification.

In addition, ever since 1979, the ABS has limited the certification to a 10 year period, and thus all Board Certified Surgeons must be re-certified every 10 years. This is acknowledgement of how perishable medical knowledge is and how rapidly technology is changing the practice of surgery. The process associated with this requirement is referred to as Maintenance of Certification (MOC). Over the intervening years, most other specialties have instituted their own policies for MOC. More important is that recently, the various other certifying boards of the ABMS have not only issued their own mandates for MOC, but are actually shortening the period for recertification, such as the requirements of the American Board of Pediatrics for "...five-year MOC cycle [which] begins January 1, 2010. On the ABP Website, you will be listed as ABP certified and designated as "Meeting current requirements for maintenance of certification . . . for a length of 5 years" (8). It is highly likely that the ABS will be soon requiring the MOC at the 5 year period, and will be including skills training beyond the initial FLS.

## SIMULATION CENTERS

In response to the above new mandates regarding simulation centers, specific skills courses, and the need for MOC, the American College of Surgeons (ACS) has responded in a twofold manner: 1. Development of a certification process to guarantee the quality of the training in a simulation center and 2. Development of a standardized skills curriculum which can meet the requirements of the RRC and ABS.

The certification of a surgical simulation center is voluntary, though clearly such a certificate would be advantageous when the routine RRC review of a surgical training program is performed. The ACS has established a stringent application and survey

process (similar to the evaluation, which includes a one day on-site survey by two surveyors, which is conducted by the RRC) which can result in a certificate as an Accredited Educational Institute (AEI). The ACS has purposefully designed the requirements to include training of multiple professionals (physicians, nurses, pharmacists, etc) to not only emphasize the importance of "inter-professional" training as a critical component of performance as a team (infra vida), but also to include documentation of training to proficiency with longitudinal (annual) analysis of the quality of the training provided. The process also includes specific resource requirements (such as minimal amount of space, number of personnel, types of simulation equipment, types of curricula, etc). As of the end of 2009, there are 48 AEI, which includes 8 centers outside of the United States. These have formed the Consortium of ACS-AEI, which held the first annual Consortium meeting in September, 2008. The strategy of this consortium is to develop a more uniform approach to surgical (skills) education in three specific areas:

1. Development of a single web-based Learning Management System (LMS). Such a database will include all the training documentation of each resident in each training program in order to establish a national norm of training which each consortium member can measure their performance against. In addition the database will include all the different courses (and curricula) which all of the consortium simulation centers teach. Analyses of the LMS database will permit the Consortium to determine where there are curriculum 'gaps' that need to be addressed. All data which is maintained in the consortium database will

- be de-identified for anonymity to insure compliance with the Healthcare Information Privacy and Portability Act (HIPPA)
- 2. Coordination of the development of curricula. Today, there has been no coordination of available curricula, and the result is that many different curricula (with different outcomes measures) exist for the same procedures, such as laparoscopic cholecystectomy, airway intubation, etc. In addition, there is no uniform method for developing a curriculum. There are many areas where curricula need to be developed, and it would be of great advantage for a number of the members to collaborate upon developing a single specific curriculum, which is then adopted by the remaining members of the consortium. This will lead to a more standardized overall surgical curriculum on a national (or international) level. It is incomprehensible why a resident trained at one institution should have a completely different education and different assessment criteria than another resident at a different institution for exactly the same surgical procedures. Even considering the different available teaching styles, individual patient variation, and surgeon preferences, there should be at least a common 'generic' approach to a surgical procedure, which then can be amplified (once the standard approach is learned) to the faculty members' preferred approach. Imagine what would occur if every pilot would have their own way of navigating a commercial jet without airway regulation and air traffic control rules; there are specific airways to fly in order to maintain safety, even though

they pilot their aircraft a bit different from one another. An added benefit of joint development of curriculum is that a multi-institutional validation study (with enough subjects to provide statistical significance) can be performed in a much quicker time frame.

3. Collaboration in Research. In much the same manner in which validation studies can be coordinated, a research agenda is being developed for new areas of simulation, including not only innovative simulators, but new types of curricula, assessment processes, and even training programs. Such an agenda will identify the areas where research needs to be performed, and help coordinate collaborative studies. Such multi-institutional studies, under the imprimatur of the ACS-AEI would have a significant competitive advantage when applying for federal funding.

The second response by the ACS to the mandates is to work within the surgical education community and develop in collaboration with the ABS and the Association of Program Directors in Surgery (APDS) an initial set of curricula: Basic Skills, Advanced Procedures, and Team Training. These curricula can become the foundation of the training programs of the Consortium of ACS-AEI and may well become the basis for skills training that will be required by the ABS for Board Certification.

The ACGME, RRC, ACS, APDS, ABS and the entire surgical education community has embarked upon a strategic revamping of the educational process for residents and surgeons. This includes not only initial training, but "retraining", such as MOC for established surgeons. The same curriculum that is being developed for MOC

can also be utilized (perhaps with minor modifications) for retraining of established surgeons when returning from a prolonged absence (*infra vida*). But more important than improving the quality and efficiency of training, implicit in this endeavor is that patient safety can be improved through a more scientific approach to surgical skills training. It is also envisioned that some of the constraints to surgical education which result from the imposition of limitations to the work hours of residents can be relieved through more efficient training in a simulation environment. This is especially applicable to the basic skills and team training, where the 'learning curve' can be moved from the bedside to the laboratory, thereby decreasing likelihood of patient error in the clinical setting.

A final trend which is occurring because of the establishment of skills training centers is that the courses and training programs that have been instituted for surgical residents are being "moved down" to the medical student level. The anticipated consequence is that when a medical student enters residency training, the basic skills will already have been learned (including inculcating team training and a "culture of safety") and more advanced training can begin earlier in their program. With this exposure, a self-selection effect could impact the makeup of the applicant pool to residency. In addition, as part of the application to surgical residency, an objective evaluation of a prospective resident's skills (in addition to their knowledge base) will be available.

#### STATE OF THE ART

To understand where the future of surgical simulation may be heading, the current state of the art needs to be reviewed, thereby providing a baseline against which the

emerging technologies can be compared in terms of their likelihood of success as well as the timing of their adoption. This will provide a pragmatic approach to monitoring and implementing the new mandates, technologies and processes.

Mandates: The current mandates and policies (supra vida) are limited to the Surgical Residency Review Committee of the ACGME, and the ACS/ABS. Other surgical specialties have not produced such requirements, although most all specialties (both medical and surgical) are addressing the issue. The MOC mandate currently stands at recertification every 10 years and there are no policies regarding other aspects of re-training. Granting of hospital privileges remains at the local hospital level, and there are no standardized requirements for documentation of skills training, currency in procedures performed, and evidence of certified training in a new procedure.

Technologies: The areas and technologies where simulation is being used are for basic skills (the 20 core skills identified by the ACS/APDS/ABS), a few advanced procedures and team training. Most simulators and skills curricula are for general surgery, anesthesiology, and nursing, though there are some simulators in flexible endoscopy, urology and obstetrics/gynecology. The greatest amount of skills training is being conducted at the basic skills level, using simple, cost-effective physical models. However, most all laparoscopic surgery training is being conducted with videoscopic trainer models, VR simulators or animal models. There are very sophisticated VR simulators for endovascular procedures, which even include patient-specific simulations. Manikin simulators have been used for specific technical skills (airway management, induction of anesthesia, conscious sedation), but their most frequent use is for clinical management and team training. The training/assessment of the non-technical skills of

the ACGME 6 competencies (physical exam, communication, etc) is mainly through the use of OSCE with patient actors, though some is being conducted with manikins.

Assessment tools include OSATS, OSCE and FLS. Others are under development.

Research: As indicated above, research is not coordinated, is driven by individuals who are inspired to create a simulation (or simulator), and frequently duplicates or competes with other existing simulators. There had been a flurry of activity in developing surgical simulators. However, due to recent reductions in available funding, that activity has slowed appreciably. The new mandates have provided an incentive for training programs to insure both adequate resources as well as simulators.

Clinical Practice: Currently, the only routine application of simulation to clinical practice in vascular procedures or in complex liver operations. Professor Marescaux of the IRCAD institute in Strasbourg, France has used simulation to pre-plan and rehearse clinical liver resection for hepatic cancer (9).

Since the 6 ACGME Competencies are so critical, the following are examples of the types of simulation used to specifically address the different competencies:

- Knowledge. This is principally traditional teaching through didactic lectures, rounds and instruction during surgery. Web-based, interactive curricula improve the quality of the training by including multi-media, especially video and animated graphics to the didactic portions
- 2. Patient Care. While traditional rounds, operating upon patients and OSCE still comprise the most common method of training, patient care is where most of the task and specific skills are conducted on manikins, models, and virtual reality simulators. Manikins are used for teaching airway

management/anesthesia skills and team training; physical models are principally for basic technical skills and specific tasks (like chest tube, etc); and mechanical or VR simulators are for specific tasks and simple procedures (like laparoscopic cholecystectomy). Training for open surgery and advanced procedures are still performed upon animal models because the simulators are not yet of sufficiently high fidelity to provide the necessary level of realism.

- 3. Communication and interpersonal skills. To date, these skills require observation and grading (with objective check lists and global rating scores). They can be trained and assessed using the OSCE format or manikins. There is a growing number of curricula to incorporate simulation of these skills, but even 'objective assessment' includes the subjective placement of an observed action into a Likert (or similar) scale in order to attempt to quantify the performance
- 4. Professionalism This is a very difficult skill to teach, and is traditionally acquired by mentorship and direct observation of effective leadership, and moral and ethical behavior in a faculty member. Some aspects of professionalism can be taught didactically, while others can be elicited in an OSCE type of activity.
- 5. Systems-based practice. This new requirement can be taught through manikin-based team training. There needs to be a clearer definition of what is meant by systems-based learning that is accepted across specialties, and if possible metrics developed so a curriculum can be developed

6. Practice-based learning and improvement. Other than attempting to adapt OSCE to continuing improvement, there are no curricula which address this issue. This is principally an issue of documentation of training and practice outcomes (e.g. morbidity and mortality conference, quality assurance assessment, etc), with evidence that a surgeon has changed/improved their practice outcomes based upon reflection of their practice

It is clear from the above examples of the use of simulation that not all of the required skills will be solely achieved by the use of simulation, though it is likely that some new creative approaches will emerge.

## **FUTURE DIRECTIONS**

Mandates: There can be little doubt that in both the near and distant future, the mandates will grow in response to the public's insatiable desire for transparency and profession's agreement for accountability in order to ensure patient safety. The specialty societies will eventually all adopt some of the simulation technologies to augment both training and assessment – these will first be required by the training programs, and then by the representative boards for certification. MOC will move to shorter time spans, very likely every 5 years, with the possibility of every three years or even automatically generated in 'real-time' during both practice and laboratory training. In addition to the specialty societies and certification boards, the local hospital privileging and credentialing committees will be adopting more comprehensive documentation of training. This will apply not only to initial and renewal privileging, but also to MOC and retraining. Eventually every category of procedure that is requested will require presentation of a certificate documenting competency. Likewise,

procedures that are not performed frequently (e.g. failure to perform to a desired number per year) will either require remediation or retraining. As more requirements are added, increasingly sophisticated simulation methods will become a very attractive alternative to practice on patients.

Very similar to MOC, the retraining will be applied to many special circumstances, such as when returning from absences due to sabbatical, maternity/paternity leave, administrative and non-medical education degrees, and duty to country. The latter is currently a significant issue for both the military and the civilian reserve physicians who are deployed to support combat operations. These surgeons are torn from the daily practice and usually begin treating patients with very different diseases or injuries from their specialty practice. The military experience indicates that it takes from 3-6 months for a returning surgeon to "re-integrate" back to their peacetime practice.

Technologies: In response to continued pressure to get completely away from use of humans and animals for training, use of simulation will continue to increase. The most basic change will be the development of 'virtual cadavers' based on 3-D reconstructed tomographic images of a specific cadaver. This virtual cadaver can be shared among a group of students who can repeatedly practice 'virtual dissection' before dissecting an actual cadaver. Over time a huge library of scans of hundreds of variations of critical anatomy will be acquired, and it may be possible to stop nearly all cadaver use at this level of medical education. With such a large library of virtual anatomy, students can learn about (and virtually dissect) all the different variations, anomalies and diseases of every organ system. Thus a very structured curriculum can be created to

ensure that each student learns about all the major variations, not just the singular characteristics of the cadaver which they happen to be assigned. This same library can be used for residents to practice virtual operations, and to gain expertise by performing the same operations with many variations, and completing operations without making errors (proficiency). This will facilitate a surgeon's progression from competency to mastery through 'experience' and exposure to a large number of variations of the basic procedure. Patient specific CT scans (with consent) could expand the library as well as increase the number of variations that would be available for training complex procedures for both residents and practicing surgeons. By the time such a library is collected, simulation technology will sufficient increases in fidelity to make even complex procedures possible.

In a similar fashion, patient actors in the OSCE will be mainly replaced by "virtual patients", which will have not only clinically relevant ("intelligent") responses to questions in the history and the ability to provide physical examination sensory input, but also will include appropriate human social, behavioral and cultural (HSBC) responses with realistic emotional representation in speech, facial expression, pose and non-verbal cues. The current research in HSBC in training the military and civilian personnel that are deployed overseas is making extraordinary progress in creating 'virtual actors' which behave and respond in a life-like manner that is nearly indistinguishable from an actual person. During surveys for the ACS-AEI, the author has queried numerous institutions as to the cost of employing patient actors for OSCE, as well as the use of cadavers for medical student and procedure training.

\$800,000 per year, depending upon the amount of such training that the specific center performs. Clearly, dramatic decreases in overall center expense can be achieved by replacing most (not all) of such training with virtual cadavers or virtual patients. In addition, education will be enhanced by the development of huge libraries of numerous variations that can provide the substrate for a well-structured curriculum that will include all the important facets of a disease state – and not continue the current hit-ormiss approach where the student only gets to learn (and be assessed) by the cadaver, actor or the on–service patient that happens to be available at the time.

VR simulators have also been adapted for pre-operative warm-up immediately before a procedure. Kahol, et al. (10) have demonstrated in the laboratory the decrease in operating time and in errors by warming up for 15 minutes before performing a procedure. This is an example of *a priori* knowledge that has been implemented in many other professions (symphony, baseball, basketball, dance, etc.) and demonstrates how warming up before a demanding activity can dramatically enhance performance. This improvement effect persists for about 30 minutes, and enhances performance of novices and experts alike. In addition, pre-op warm-up is needed before every procedure since the increased psychomotor performance and increased attention and near-term memory does not carry over from one operation to the next, mainly due to the waning of the improvement effect beyond 30 minutes.

Manikins will all become tetherless and reach greater degrees of visual and physical (e.g. tissue characteristics, bleeding, etc) fidelity to a point where they will incorporate not only physiology feedback, but enable performance of more advanced procedures as well. Team training is moving out from the laboratory and into the

hospital environment (in-situ training) by placing the manikin in an ICU bed, in the ER, or in other actual environments. Preliminary investigations demonstrate that in-situ training is valuable in identifying system errors in addition to enhancing communication and professionalism. Because the simulation center has all the equipment, drugs, and instruments correctly prepared for the training episode, system errors like the wrong dose of medication stored at the nursing station, or not having the correct connector or instrument available on the floor are not discovered during laboratory training but rapidly appear during in-situ training. In addition, inter-professional team training will be extended to train and assess continuity of care. The current curricula for team training in the ER, ICU, OR situation will be strung together to ensure the proper 'hand off' of the patient from one team to the next. A typical type of scenario could include stabilization of the patient by the ER team, hand-off to the operating room team, then safe transfer of the patient to the ICU post-operatively. Key issues include connectivity of instrumentation (e.g. ensure the endotracheal tube can connect to the ventilator, etc.), transmission of critical information (laboratory data, previously administered drugs, etc.) and communication of completed or continued treatment protocols.

Tele-simulation is being explored in order to provide at a remote location, the same level of training that occurs at a major medical center location. With a smaller staff, a remote hospital coordinates with the director and faculty of the simulation center to conduct a training course at the local institution over the internet. Depending upon the type of course, a simulator or manikin can be shipped to the remote location (reducing procurement costs associated with very expensive equipment intended for only occasional use). Once the remote staff is trained, the large expense in time, travel,

and actual cost for repeated training and MOC can be substantially decreased by having them participate in teaching roles in training and evaluation of additional students/faculty at the remote location. This is clearly going to be a major issue as the need for MOC compliance significantly increases

Crossing the boundaries between virtual patients/cadavers and tele-simulation and training, there will be an increase in the use of virtual environments (VE), such as Second Life (SL). This technology can provide a complete representation of a simulation center or conference room on the Internet in one of the VEs which are now commercially available, the best known of which is the free SL "world". Different from games that are played on the internet, SL only provides the "world" or terrain and the 'tools' such as virtual person (avatar), methods of 'travel' throughout the world, and methods of interaction with various objects such as simulators, projections of powerpoint presentations, video clips etc. Then individual people can build their specific place, such as a store to actually purchase 'clothes' to change the appearance of your avatar, or a conference room to hold virtual meetings, and in particular complete buildings that can exactly replicate an actual simulation center. Then the students can come to the virtual center and practice the simulation without leaving home or the office. While this is available at a relatively simplistic level at this time, rapid technological advances are increasing the fidelity (and believability) of such VEs. While most training will not occur in a virtual simulation center, the new generation of residents and surgeons are embracing this technology and are very comfortable working there. Currently the military has a program called Virtually Home for soldiers with Traumatic Brain Injury and Post Traumatic Stress Disorder (TBI/PTSD) in which the warriors are

able to return to their home city and come daily to the virtual "warrior transition unit" office and participate in their military duties, or have a rehabilitation session with their doctor, psychologist, or rehabilitation therapist.

Research The most important aspects of research will be identifying the 'gaps' in the current training and assessment capabilities and products, and then to establish a coordinated, multi-institutional approach that will provide more researchers to solve the problems as well as a larger pool of subjects to validate the efficacy. Such an approach also will (hopefully) reduce the redundant efforts of many different researchers and companies that are developing curricula/simulators. The current model has resulted in different outcomes measures and assessment tools and dramatically different training for the same procedures at many different institutions. This can be improved with establishment of a more uniform training curriculum. It is essential to come to consensus on core curriculum issues that can provide a common foundation for all surgeons, and then for individual institutions/faculty to modify such a foundation to local needs or preferences.

Clinical Practice: While the value of simulation based training and assessment in the laboratory environment will continue to provide an enormous benefit for both quality of healthcare and patient safety, the greater long term benefit will be realized as simulation becomes integrated into clinical practice. The procedures which are practiced in the laboratory will soon be instantiated in clinical practice as patient-specific pre-operative planning and surgical rehearsal. Eventually, nearly every procedure will be rehearsed on the image of the patient just before the surgeon conducts the actual procedure on the patient. Following the rehearsal, pre-op warm-up will be used to adequately prime

the surgeon for optimal execution of the operation. During the procedure there will be the equivalent of a "black box" that will continuously monitor performance and provide feedback information and suggestions (a "virtual mentor") as well as record the performance of the surgeon's motions and the coordination of the operative team which will be automatically available as a quantitative record of the of the surgery to provide continuous documentation for quality improvement, patient safety and maintenance of certification.

## CONCLUSION

The future of surgical education, skills training and assessment and simulation is just beginning to be incorporated into the fabric of surgery. This represents a true revolution in education, and will set the framework for the next century of surgical education. It is critical that an enormous effort be expended to ensure that a uniformity of approach and quality of training emerges, preventing the fragmented process of education that exists. If we do not achieve such inter-operatilty, it will be another century before such an opportunity occurs.

These changes must be implemented across all disciplines and incorporated in laboratory training, in-situ training, and daily clinical practice to a point where simulation becomes automatically embedded into the very culture of surgery. The reward for such an extraordinary effort will be an unprecedented level of quality of care and of patient safety.

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